HIA/Hearing Industries Association

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Srinivas ''Nandu'' Nandkumar,
Ph.D. Branch Chief
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation Center for Devices and Radiological Health
U.S. Food & Drug Administration

CC:
Eric Mann, M.D., Ph.D.
Clinical Deputy Director
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation Center for Devices and Radiological Health
U.S. Food & Drug Administration

Cherish Giusto,
Au.D. Audiologist
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation Center for Devices and Radiological Health
U.S. Food & Drug Administration

Dear Dr. Nandkumar:

As stakeholders in the hearing healthcare community, the Hearing Instruments Association (HIA) appreciates the opportunity to provide feedback to the U.S. Food and Drug Administration (FDA) regarding the Bose Decision Summary. We support FDA's decision to require a 510(k) for other products within this classification and to establish a risk classification in line with traditional hearing aids. We are also encouraged by the fact the cleared device has safe and efficacious compression strategies.

We do, however, respectfully wish to convey several concerns. First, according to the Decision Summary, no acceptance criteria are defined for full on or maximum gain. This can be problematic because, without an upper limit, the amplified sound levels from the hearing device could reach beyond the stated indication for mild-to-moderate hearing impairment. Any self-fitting or over-the-counter hearing aids for mild-to-moderate hearing loss should have SPL and a full-on gain limit of 25dB, as measured in a 2cc coupler with an input of 50 dB, as recommended in the Hearing Professional Associations "Consensus Paper," which was endorsed by HIA. This threshold has been defined by using the NAL-NL2 gain estimator to accommodate comfortable bearing of a soft input for an individual with flat moderate hearing loss who is undertaking binaural usage and did not have previous experiences with amplification devices.

Second, we are concerned with the maximum power output level (MPO) of 120dB Sound Pressure Levels (SPL). As FDA is aware, unsafe listening practices and over-amplification have been increasingly noted as causes of noise induced hearing loss. MPO serves to limit sound to levels that are neither damaging nor uncomfortable for the wearer and also protects against over amplification of higher-level inputs occurring more consistently over a longer duration. Adjusting MPO properly is therefore critical to the safe use of hearing aids. As noted in the Associations' Consensus Paper, a study published in the

International Journal of Audiology in 2017 estimated the safe output SPL for sound amplification devices to preserve hearing sensitivity after amplification usage. That study determined that the safe overall output SPL for a flat 55 dB hearing loss is no greater than 111 dB. Therefore, it was recommended that the peak (or maximum) power output be no greater than 110 dB SPL, when measured as per ANSI S3.22-2014, for mild to moderate hearing losses.

MPO and gain must be considered together to enable safe and effective use of the device. We believe the recommended gain and output levels, as contained in the Consensus Paper, will provide adequate gain for audibility and comfortable listening. At the same time, those requirements together with input (or better) compression strategy will ensure protection
against further damages to the user.

In addition, HIA is concerned that the Phase II clinical study, as described in the Decision Summary, does not provide enough evidence of effectiveness of the self-fitting method given the study's initial reliance on professionals for fitting. As stated in the Summary (emphasis added), *"All subjects participated in three clinic visits (1-First Fit, 2-Fine-Tuning, and 3-Assessment) as well as several weeks of Bose prototype hearing aid use in the field.* ***During the first two sessions, all subjects were fit professionally with a prototype version of the Bose Hearing Aid by one of several participating licensed audiologists using custom professional fitting application.*** *Subjects were then assigned for a one-month field trial to either a "Pro-Fit" Group[...} or a "Self-Fit" Group."* Thus, subjects assigned to the "Self-Fit" Group appear to have been able to adjust the features of the device only within the parameters defined by the audiologist in the "I-First Fit" and "2-Fine-Tuning" clinical visits rather than "self-fitting'' the device from the beginning without professional support at all. This does not reflect the actual real-world experience.

Additionally, the "Self-Fit" Group had almost three times higher experienced users (as opposed to new hearing aid users) than the ''Pro-Fit'' Group. Research has shown that experience with amplification devices has a very strong correlation with satisfaction 1 as well as ability of the user to adjust the settings of the hearing aid. As such, HIA has concerns the data the study relies upon may not accurately reflect the ability of treatment-naive hearing patients to adequately "self-fit'' without the assistance of a licensed hearing professional.

Finally, FDA's classification decision appears to be based on adherence to the CTA 2051 standard. As the standards explicitly state, they are intended for personal sound amplification =-\- performance (PSAP) for personal sound amplification and/or enhancement. CTA-2501, § 1 (2017). As a result, the CTA 2051 standards are designed for amplification quality control purposes and do not focus on audibility, intelligibility, or hearing assistance. In particular, they fail to provide meaningful protections with respect to gain (no stated recommendation) and excessive maximum power output limitation (120dB SPL). Therefore, adoption of these standards could adversely impact safety and effectiveness and would jeopardize the hearing health of consumers who purchase these devices.

In summary, to ensure safety and effectiveness of self-fitted hearing aids, for mild to moderate degree of hearing loss, we want to emphasize the importance of certain product requirements
for any hearing aid intended for users with mild-to-moderate hearing loss without the involvement of a licensed hearing care professional, including:

- HFA full-on gain limit of25dB, measured with an input of 50 dB SPL; and

- Peak (or maximum) power output no greater than 11 0dB SPL when measured in a 2-cc coupler as per ANSI S3.22-2014.

We would urge FDA to take this feedback into consideration as it develops a proposed regulation for over-the-counter hearing aids. We are committed to engaging with the FDA and would welcome the opportunity to answer any questions or concerns you may have.

Sincerely,

Brandon Sawalich
HIA Board Chairman President
Starkey Hearing Technologies

Kate Carr
President
HIA